



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/037,792 03/10/98 ROSENBERG

J 04801168

HM22/0710

HERBERT B. KEIL
KEIL & WEINKAUF
1101 CONNECTICUT AVENUE, N.W.
WASHINGTON DC 20036

EXAMINER

WERNAN, F

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

07/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/037792

Applicant(s)

ROSENBERG

Examiner

WEEMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 4/3/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 111; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 5-12 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 5-12 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1617

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9,12 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi.

Choi et al teach the addition of bacitracin into a hot melt of a poly (ortho) ester (column 36, lines 52-55). Extrusion is specified (column 28, lines 17-24). Other pharmaceuticals are specified (column 29, line 30 et seq.)

Applicants argue that two phases are not taught. However, the examiner takes notice that the zinc bacitracin in Choi et al has a melting point of 250°C. Thus, the drug remains in the solid phase.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-10,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al.

The examiner takes notice that bacitracin has a bitter taste.

Art Unit: 1617

The examiner takes further notice that adding flavor to disguise the taste of bitter drugs is well-known in the art. Thus, it would have been obvious to one of ordinary skill to add a flavor to the composition of Choi et al to disguise the bitter taste of bacitracin.

Claim 11 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 11 of prior U.S. Patent No. 6001391. This is a double patenting rejection.

Claims 5-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a drug in a second phase or in both phases, does not reasonably provide enablement for a drug only in the matrix. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicants do not disclose a second phase such as a particulate that does not contain a drug.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11 it is unclear as to whether the same active is in both phases or whether one drug can be in one phase and a second drug in the second phase.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on M-F from 9AM to 5PM.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M.Moezie, can be reached on (703) 308-0570. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/sg

June 26, 2000


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500